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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

FORMAN, BETTY J

ART UNIT

PAPER NUMBER

1634

DATE MAILED: 09/04/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/091,296	OBERHARDT, BRUCE	
	Examiner	Art Unit	
	BJ Forman	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 March 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 06 May 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>03/02</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Preliminary Amendment

1. The preliminary amendment filed 6 March 2002 is acknowledged and had been entered. Claims 21-25 have been cancelled. Claims 1-20 are pending.

Specification

2. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 120 as follows: An application in which the benefits of an earlier application are desired must contain a specific reference to the prior application(s) in the first sentence of the specification of in an application data sheet (37 CFR 1.78(a)(2) and (a)(5)). The specific reference to any prior nonprovisional application must include the relationship (i.e., continuation, divisional, or continuation-in-part) between the applications except when the reference is to a prior application of a CPA assigned the same application number.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
3. Claims 1-20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
 - a. Claims 1-20 are indefinite for the repeated recitation "the said" which is redundant and therefore confusing.
 - b. Claims 8-9, 13-17, 19-20 are indefinite in Claim 8 because the claim is drawn to the element of Claim 1 comprising a base, a means for channeling light and means for detecting light. However, it is unclear whether the structural components recited in Claim 8 are integrated into the element of Claim 1 and if so, how they physically relate to the components

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of Claim 1. Furthermore, it is unclear whether the sample well and reaction space of Claim 8 are the same or different from sample well and reaction volume recited in Claim 1.

c. Claim 11 is indefinite for the recitation "the reaction slide" because the recitation lacks proper antecedent basis in Claim 2.

d. Claims 19 and 20 are each indefinite for the recitation "the said spacer" because the recitation lacks proper antecedent basis in Claim 8.

e. Claim 20 is indefinite as being of improper dependent form for failing to further limit the subject matter of Claim 19.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-6, 8-11, 13, 14, 16 and 18-20 are rejected under 35 U.S.C. 102(b) as being anticipated by Columbus (US 4,323,536).

Columbus discloses a test device and a method of testing, that uses a plurality of test elements, all elements being supplied analyte from a single quantity of liquid. The liquid is

conveyed to the test elements by capillary transport and means for venting are provided.

Columbus discloses support (12), cover (14) and peripheral sealing (20) with capillary spacing of 25 to 500 microns; liquid absorbent; selecting degree of hydrophilicity; and scanning the test device with a photometer or fluorometer in either reflective or transmissive mode. (see abstract; col. 2, lines 23-29; col. 3, lines 15-34; col. 4, lines 21-35; col. 5, lines 31-45; Figures 1-3). Thus, monitoring means, light channelling means and detection means are inherent in Columbus.

Columbus does not specifically disclose or suggest: (i) use of a permanent magnet, an electromagnet and inert magnetic particles; (ii) an optical fiber assembly; (iii) an end cover; (iv) an overhanging liquid absorbent matrix; (v) elements 14 and 20 as a one piece design; and (vi) monitoring filling of the test device.

Claims 1-6, 8, 9, 11-14 and 18-20 are rejected under 35 U.S.C. 102(b) as being anticipated by Shanks et al. (WO 86/00141).

Shanks et al. disclose a testing device possessing a cavity or cavities each having a dimension small enough to enable sample liquid to be drawn into the cavity by capillary action, wherein a surface of the cavity carries an immobilized reagent and wherein the surface is a surface of a transparent solid plate to act as a light-transmissible waveguide and forming a wall of the cavity. Some forms of the device use a light-absorbing or opaque or reflective wall opposite the capillary cavity. Capillary spaces less than about 1mm; cover (5); overlay (7); base (6); hydrophobic coating; fiber optics and air vents are also disclosed. (see pages 3, 4, 8, 9, 16, 23, 24 and Figure 1). Shanks et al. do not specifically disclose: (i) use of a permanent magnet, an

electromagnet and inert magnetic particles; (ii) an end cover; (iii) a liquid absorbent matrix; (iv) monitoring filling of the test device; or (v) design per instant claim 17.

Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by McCormick (US 3,233,975).

McCormick discloses a prothrombin assay and a microreaction chamber comprising two interconnecting liquid receiving pockets (one for sample (31) and one for reagent (29)) one of which has sufficiently narrow sides so as to have capillary action. (see col. 2, lines 50-59; col. 3, lines 11-15; col. 4, lines 59-64).

Claims 1-4, 7-9, 13 and 14 are rejected under 35 U.S.C. 102(b) as being anticipated by Lilja et al. (US 4,088,448).

Lilja et al. disclose a cuvette with a cavity which is defined by two planar surfaces; reagent in the cavity in an amount related to the volume of the cavity; and sample being drawn into the cavity by capillary forces mixed with reagent therein spontaneously or by vibrations, whereupon optical analysis takes place directly through the two planar surfaces. Parallel and series connected cavities are disclosed. Spacing elements made of ferromagnetic material may have a mixing function if the cuvette is placed in a variable magnetic field. Basic photometer configurations are inherent. (see abstract; col. 1, lines 6-57; col. 2, lines 5-6 and 65-67; col. 3, lines 17-53; col. 4, lines 22-26 and 43-51). Lilja et al. do not disclose: (i) a liquid absorbing matrix; (ii) reflectometry/nephelometry; (iii) fiber optics assembly; (iv) an end cover; (v) the design of instant

claim 17; (vi) monitoring filling of the cuvette; (vii) hydrophilicity treatment; (viii) the instant spacers; or (ix) inert magnetic particles.

Claims 1, 10 and 18 are rejected under 35 U.S.C. 102(b) as being anticipated by Rapkin et al. (US 4,678,757).

Rapkin et al. disclose one step methods for whole blood separation and analysis comprising capillary and longitudinal transport of blood through a test device from a sampling area (66) to a testing area (64). Barrier materials (118) confine migration to a limited pathway. (see col. 1, lines 37-39; col. 4, lines 64-66; col. 5, lines 7-10 and Figures 9 and 17.)

Claims 1-4, 6, 8-11, 13-16, 19 and 20 are rejected under 35 U.S.C. 102(e) as being anticipated by Blatt et al. (US 4,761,381).

Blatt et al. describe a flow metering capillary device for controlled fluid flow of test liquid comprising oppositely disposed top and bottom surface layers defining therebetween a capillary zone of intended liquid transport of a test liquid, said top and bottom surface layers being spaced apart at a distance no greater than which will maintain a capillary flow of said test liquid therebetween and wherein said capillary zone is divided into a sample test chamber containing interactive material capable of reaction with a component of the test sample to provide a detectable response, e.g. by colorimetry or reflectometry, and optionally, an overflow comprising an absorbent means.

Claims 1-6, 8, 9, 11, 19 and 20 are rejected under 35 U.S.C. 102(e) as being anticipated by Hillman et al. (US 4,756,884).

Hillman et al. describe a capillary flow element for detecting the presence of an analyte in a fluid sample, comprising a housing containing an inlet port, a chamber unit, and a capillary unit. Orifices are provided which connect the capillary pathway to the atmosphere at one or more sites, thereby allowing one to terminate the flow up to that site, so that movement may be stopped subject to the initiating movement. Detection comprising color, absorbance, fluorescence, etc. means are disclosed. Capillary diameters in the range of about 0.01mm to 2mm are disclosed.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Columbus (US 4,323,536) or Shanks et al. (WO 86/00141) each in view of Adler (US 3,650,698) and McCormick (US 3,233,975).

Columbus, Shanks et al. and McCormick have been described *supra*.

Adler discloses an intensifying agent comprising opaque magnetic particles disposed on a suitable carrier means. A sample-reagent-intensifying agent mixture is subjected to rotating magnetic fields with the result that the moving magnetic particles promote mixing and are also operative to collect one or more fibrin strands when measuring prothrombin time.

It would have been obvious to modify the test devices and methods of Columbus or Shanks et al. by performing a prothrombin assay as suggested by both Adler and McCormick and to employ magnetic particles in a rotating field such as might be produced by a combination of electromagnet and permanent magnet to "intensify" assay results and/or improve mixing as suggested by Adler.

Claims 15-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Columbus (US 4,323,536) or Shanks et al. (WO 86/00141) each in view of Adler (US 3,650,698) and McCormick (US 3,233,975) and further in view of Berger et al. (US 4,780,280).

Figures 1 and 2 of Berger et al. disclose designs for diagnostic elements comprising the instant claimed absorbent matrices and end covers which provide improved liquid transfer.

It would have been obvious to modify the test devices of either Columbus or Shanks et al. by using end covers (20) and/or absorbent matrices (19 and 50) as suggested by Figures 1 and 2 of Berger et al. to improve liquid transfer. Other features of the instant invention not specifically disclosed by the references are conventional and, therefore, deemed obvious.

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Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-20 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-16 of U.S. Patent No. 6,197,494. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are drawn to an element (i.e. apparatus) comprising a channel structure defining a sample well and reaction volume in communication with each other wherein the channel structure has a geometry causing a liquid sample placed in the sample well to be drawn into the reaction volume. The claims merely differ in that the patent apparatus further comprises a permanent magnet and electromagnet. However, the open language "comprising" of the instant claims encompasses the additional elements of the patent apparatus. Therefore, the instantly broadly claimed element is obvious in view of the patent apparatus.

Claims 1-18 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-9 of U.S. Patent No. 4,849,340. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are drawn to an element (i.e. analytical system) comprising a channel structure defining a sample well and reaction volume in communication with each

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other wherein the channel structure has a geometry causing a liquid sample placed in the sample well to be drawn into the reaction volume. The claims merely differ in that the patent apparatus further comprises a permanent magnet and electromagnet. However, the open language "comprising" of the instant claims encompasses the additional elements of the patent apparatus. While the patent apparatus is drawn to performing a prothrombin time assay, the intended use does not patentably distinguish an apparatus.

A claim containing a "recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus" if the prior art apparatus teaches all the structural limitations of the claim. *Ex parte Masham*, 2 USPQ2d 1647 (Bd. Pat. App. & Inter. 1987).

Therefore, the instantly broadly claimed element is obvious in view of the patent apparatus.

Claims 1-18 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-5 of U.S. Patent No. 5,658,723. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are drawn to an element (i.e. analytical system) comprising a channel structure defining a sample well and reaction volume in communication with each other wherein the channel structure has a geometry causing a liquid sample placed in the sample well to be drawn into the reaction volume. The claims merely differ in the arrangement of limitations and the intended use for the patent system. However, the courts have stated that the intended use of a device does not distinguish the device.

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Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BJ Forman whose telephone number is (703) 306-5878. The examiner can normally be reached on 6:30 TO 4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (703) 308-1119. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 308-8724 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.



BJ Forman, Ph.D.
Primary Examiner
Art Unit: 1634
September 2, 2003